

SEP 11 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K061795

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer: Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714
Attn: Pamela A. Jurga
Tel: 302-631-8891

Date of Preparation: June 23, 2006

2. Device Name / Classification

- Dimension Vista™ PBNP reagent cartridge/ Class II
- Dimension Vista™ PBNP calibrator/ Class II

3. Identification of the Predicate Device

- Roche Diagnostics Elecsys® proBNP immunoassay and proBNP CalSet Calibrator (K032646/K022516).

FDA Guidance Document(s):

- "Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers" - 11/30/2000

4. Device Description(s):

Method

The PBNP method is a one-step sandwich chemiluminescent immunoassay based on Luminescent Oxygen Channeling Immunoassay (LOCI™) technology. LOCI™ reagents include two latex bead reagents and a biotinylated polyclonal antibody fragment which recognize an epitope located in the

N-terminal part of proBNP. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The second bead reagent (Chemibeads) is coated with a second antibody specific for a second independent epitope on NT-proBNP and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a particle/NT-proBNP/biotinylated antibody sandwich. Sensibeads then are added and bind to the biotin to form a bead-aggregated immunocomplex. Illumination of the complex by light at 680 nm generates singlet oxygen from Sensibeads, which diffuses to the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is directly proportional to the concentration of NT-proBNP in the sample.

Calibrator

The PBNP Calibrator is a frozen liquid product containing synthetic human N-terminal pro-brain natriuretic peptide in a bovine albumin matrix with stabilizers and preservative. The kit consists of eight vials, two each of four levels (A, B, C, and D), 1.0 mL per vial for levels A, C, and D and 1.5 mL per vial for level B. Description of the manufacturing, value assignment and stability testing processes are provided in Section 21.

5. Device Intended Use:

Method

The PBNP method is an *in vitro* diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the Dimension Vista™ System. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

Calibrator

The NT-proBNP (PBNP) Calibrator is an *in vitro* diagnostic product intended to be used for calibration of N-terminal pro-brain natriuretic peptide (PBNP) method for the Dimension Vista™ System.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:

These products are substantially equivalent to other B-type natriuretic peptide test systems, such as the Roche Diagnostics Elecsys® proBNP immunoassay and proBNP CalSet Calibrator (K032646/K022516).

See examples of the predicate device labeling in Section 12.1.

Comparison to Predicate Device:

Method

The proposed Dade Behring Dimension Vista™ PBNP method and the predicate Roche Diagnostics Elecsys® proBNP immunoassay are both *in vitro* diagnostic immunoassays intended for the quantitative measurement of N-terminal pro-brain natriuretic peptide in human serum and heparinized plasma. See Section 12.1 for a copy of the predicate labeling. The Dade Behring Dimension Vista™ PBNP Flex® method utilizes the Roche polyclonal (sheep) antibody/antigen set. A summary of the features of the two assays is included in the table below.

Feature	Dimension Vista® PBNP	Roche Elecsys® proBNP (K032646/K022516)
Intended Use	For the <i>in vitro</i> quantitative measurement of N-terminal pro-brain natriuretic peptide in human serum and plasma. In individuals suspected of having congested heart failure (CHF) measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.	For the <i>in vitro</i> quantitative determination of N-terminal pro-brain natriuretic peptide in human serum and plasma. The Elecsys proBNP assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure.
Assay Type (detection)	immunoassay (chemiluminescent)	immunoassay (electrochemiluminescent)
Reportable Range	5 - 35,000 pg/mL	5 - 35,000 pg/mL
Antibody	Roche Diagnostics' polyclonal (sheep) antibody	polyclonal (sheep) antibody
Cut-off	125 pg/mL for patients less than 75 years and 450 pg/mL for patients 75 years and older	125 pg/mL for patients less than 75 years and 450 pg/mL for patients 75 years and older
Analytical Sensitivity	≤ 5 pg/mL	5 pg/mL
Functional Sensitivity	≤ 30 pg/mL	< 50 pg/mL
Analytical Specificity	Natercor® shows no significant cross reactivity, 0 or 125 pg/mL NT-proBNP; sixteen other substances show no significant cross reactivity	Natercor® shows no significant cross reactivity, 300 pg/mL or 3000 pg/mL NT-proBNP; sixteen other substances show no significant cross reactivity
Interferences	No significant interference from: bilirubin ,conj. up to 60 mg/dL bilirubin, unconj. up to 60 mg/dL	No significant interference from: bilirubin up to 35 mg/dL hemoglobin up to 1.4 g/dL

	hemoglobin up to 680 mg/dL triglycerides up to 3000 mg/dL rheumatoid factors up to 500 IU/mL	triglycerides up to 4000 mg/dL rheumatoid factors up to 1500 IU/mL
Reference	Roche NT-proBNP antibody (1-76)	Roche NT-proBNP antibody (1-76)
Hook Effect	No effect up to 400,000 pg/mL	No effect up to 300,000 pg/mL
Calibration Interval	30 days - same reagent lot	30 days - same reagent lot
Sample Volume	8 uL	20 uL

Calibrator:

Feature	Dimension Vista® PBNP	Roche Elecsys® proBNP (K032646/K022516)
Intended Use	PBNP method calibration	proBNP method calibration
Analyte	Synthetic NT- proBNP	Synthetic NT-proBNP
Matrix	Bovine albumin	Equine serum
Form	Liquid, frozen	Lyophilized
Volume	8 vials, 2 at each level, 1.0 mL per vial for level A, C and D, 1.5 mL per vial for level B	1 mL for each level
Levels	4 levels (0, 125, 1500, and 36750 pg/mL)	2 levels (140 and 2700 pg/mL)

Proposed Labeling:

See Section 13.1 for a copy of the proposed Dimension Vista™ PBNP Flex® reagent cartridge and PBNP Calibrator labeling.

Note: Section 22 contains an additional set of draft labeling for CLIA categorization purposes.

Comments on Substantial Equivalence:

Method

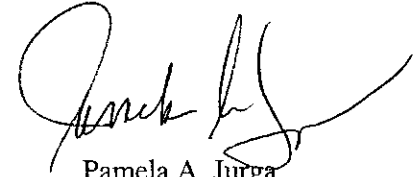
Both the Dade Behring Dimension Vista™ PBNP and the Roche Elecsys® proBNP immunoassays are intended for the quantitative determination of NT-proBNP. Comparative data for human serum and plasma samples demonstrate good analytical and clinical agreement between the methods.

Calibrator

The Dade Behring Dimension Vista™ PBNP calibrator is similar to other calibrator products associated with their assays, such as the Roche Elecsys® proBNP CalSet calibrator.

Conclusion:

The Dade Behring Dimension Vista™ PBNP Flex® method and the predicate Roche Elecsys® proBNP immunoassay (K032646) are substantially equivalent based on their intended use and performance characteristics as described above. The calibrator product is also equivalent in its design and intended use with its respective assay systems.



Pamela A. Jurga
Regulatory Affairs and Compliance Manager
June 23, 2006



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Pamela Jurga
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

SEP 11 2006

Re: k061795
Trade/Device Name: Dimension® Vista™ NT-proBNP (PBNP) Flex®
reagent cartridge method
Dimension® Vista™ NT-proBNP (PBNP) calibrator
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC, JIT
Dated: August 14, 2006
Received: August 15, 2006

Dear Ms. Pamela Jurga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

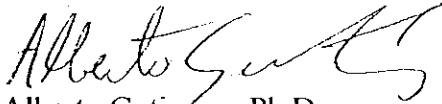
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Alberto Gutierrez', with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061795

Device Name:

- Dimension® Vista™ NT-proBNP (PBNP) Flex® reagent cartridge method
- Dimension® Vista™ NT-proBNP (PBNP) calibrator

Indications For Use:

Method

The PBNP method is an *in vitro* diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the Dimension Vista™ System. In individuals suspected of having congestive heart failure (CHF) measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

Calibrator

The Dimension Vista™ NT-proBNP (PBNP) calibrator is an *in vitro* diagnostic product for the calibration of the N-terminal pro-brain natriuretic peptide (PBNP) method on the Dimension Vista™ System.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Page 1 of 1

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061795